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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )

Michael Lester Kerns, et al )

For: RUBBER FOR BABY BOTTLE )

NIPPLES, PACIFIERS AND SYRINGE )

PLUNGERS )

Serial No.: 10/808,856 )

Filed: ~~July 21, 2009~~ )

3/25/04 T.W. )

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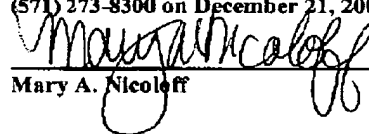
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Docket No. DN2001-192D01

Art Unit: 3763

Examiner: Patel, Pritesh Ashok

BEFORE THE BOARD OF PATENT  
APPEALS AND INTERFERENCESI hereby certify that this correspondence is  
being facsimile transmitted to the United States  
Patent and Trademark Office to fax number  
(571) 273-8300 on December 21, 2009.  
Mary A. NicoloffCommissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

## APPELLANTS' BRIEF

Appellants by virtue of their Notice of Appeal filed on October 21, 2009, file their Brief in response to the Final Rejection of all the claims pending in the subject patent application. Please charge the \$540.00 fee for filing this Brief required under 37 CFR §1.17(c) to Deposit Account No. 07-1725. The Commissioner is also hereby authorized to deduct any additional fees that may be required, or to credit any overpayment, to Deposit Account No. 07-1725.

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**REAL PARTY IN INTEREST**

The Goodyear Tire & Rubber Company is the real party in interest regarding the subject appeal since the inventors have assigned all of their rights in the subject invention to The Goodyear Tire & Rubber Company.

**RELATED APPEALS AND INTERFERENCES**

An appeal of the rejection of the claims pending in United States Patent Application Serial No. 10/868,160, is currently before the Board of Patent Appeals and Interferences. Serial No. 10/686,160 and the subject patent application (Serial No. 10/808,856) are both divisional applications of Serial No. 10/273,918 which is now issued as United States Patent 6,871,751. United States Patent 6,871,751 claims baby bottle nipples that are made with polyisoprene rubber that is synthesized utilizing a neodymium catalyst system. Serial No. 10/868,160 claims pacifiers that are made with polyisoprene rubber that is synthesized utilizing a neodymium catalyst system and the present patent application claims syringes having stoppers that are made with polyisoprene rubber that is synthesized utilizing a neodymium catalyst system. Accordingly, United States Patent 6,871,751, Serial No. 10/868,160 and the present patent application claim baby bottle nipples, pacifiers, and syringe stoppers, respectively, all of which are made utilizing neodymium polyisoprene rubber.

**STATUS OF THE CLAIMS**

All of the claims pending in the subject patent application (claims 1-19) are under final rejection. The rejections of claims 1-19 are being appealed. A complete copy of all pending claims are in the Claims Appendix to this Brief.

**STATUS OF AMENDMENTS**

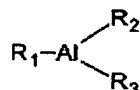
Claim 4 was amended and claim 19 was added by an Amendment under 37 C.F.R. §1.111 mailed on April 23, 2009. This amendment was entered by the Examiner and no further amendments have been filed subsequent to the final rejection.

**SUMMARY OF CLAIMED SUBJECT MATTER**

Claim 1 specifically calls for a syringe which is comprised of a barrel having a fluid chamber, a proximal end, a distal end and an elongated tip extending from said distal end

having a passageway therethrough in fluid communication with said chamber, and an elongated plunger rod including a stopper slidably positioned in fluid-tight engagement with an inside surface of said chamber for drawing fluid into and out of said chamber by movement of said plunger relative to said barrel, wherein the stopper is comprised of neodymium polyisoprene rubber (see the specification a page 6, line 32 to page 7, line 8).

Claim 4 specifically calls for a syringe which is comprised of a barrel having a fluid chamber (see the specification at page 6, lines 32-33), a proximal end, a distal end and an elongated tip extending from said distal end having a passageway therethrough in fluid communication with said chamber (see the specification at page 7, lines 1-3), and an elongated plunger rod including a stopper slidably positioned in fluid-tight engagement with an inside surface of said chamber for drawing fluid into and out of said chamber by movement of said plunger relative to said barrel (see the specification at page 7, lines 3-7), wherein the stopper is comprised of neodymium polyisoprene rubber (see the specification at page 7, lines 8), wherein the stopper has ribs (see the specification at page 36, lines 16-19), wherein the neodymium polyisoprene rubber is made with a catalyst system that includes (1) an organoaluminum compound (see the specification at page 15, line 30), (2) an organoneodymium compound (see the specification at page 15, lines 30-31), and (3) at least one compound that contains at least one labile halide ion (see page 15, lines 31-32), and wherein the organoaluminum compound is of the structural formula:



wherein  $\text{R}_1$  is selected from the group consisting of alkyl, alkoxy, aryl, alkaryl, arylalkyl radicals and hydrogen, wherein  $\text{R}_2$  is selected from the group consisting of alkyl, aryl, alkaryl, arylalkyl radicals and hydrogen, and wherein  $\text{R}_3$  is selected from a group consisting of alkyl, aryl, alkaryl and arylalkyl radicals (see the specification at page 16, lines 3-15).

Claim 16 specifically calls for a syringe mixing and delivery system comprising a first barrel having an open end and an opposite delivery end defining a delivery passage; a reciprocable stopper sealingly disposed in said first barrel to define a first chamber between said delivery passage and said reciprocable stopper for containing a first constituent in said first chamber; a second barrel that is sized to be disposed in said first barrel and that has an open end and an opposite discharge end defining a discharge passage; a slidable plunger sealingly disposed within said second barrel to define a second chamber between said

discharge passage and said slidable plunger for containing a liquid second constituent in said second chamber; and fluid transfer connector means for operatively connecting said second barrel with said reciprocable stopper to permit flow of said liquid second constituent through said stopper from said second chamber to said first chamber to mix with said first constituent when said second barrel discharge end and plunger are moved closer together whereby subsequent movement of said second barrel and reciprocable stopper together toward said delivery passage of said first barrel expresses the mixed constituents out of said first chamber through said delivery passage, wherein said reciprocable stopper and plunger are comprised of neodymium polyisoprene rubber (see the specification at page 10, line 16 to page 11, line 7).

**FIRST GROUND OF REJECTION TO BE REVIEWED ON APPEAL IS THE  
REJECTION OF CLAIMS 1, 2, 16 AND 17 UNDER 35 U. S.C. §103(a)**

The first ground of rejection to be reviewed on appeal is the rejection of claims 1, 2, 16 and 17 under 35 U.S.C. §103(a) as being unpatentable over Case (United States Patent 4,405,317) in view of Takeuchi et al (United States Patent 4,433,107).

**SECOND GROUND OF REJECTION TO BE REVIEWED ON APPEAL IS THE  
REJECTION OF CLAIMS 3-15, 18 AND 19 UNDER 35 U. S.C. §103(a)**

The second ground of rejection to be reviewed on appeal is the rejection of claims 3-15, 18 and 19 under 35 U.S.C. §103(a) as being unpatentable over Case (United States Patent 4,405,317) in view of Takeuchi et al (United States Patent 4,433,107) in further view of Throckmorton et al (United States Patent 3,541,063).

**ARGUMENT**

**The Rejection under 35 U.S.C. 103(a) over Case in view of Takeuchi.**

**(1) The Rejection of Claims 1, 2, 16 and 17**

Claims 1, 2, 16 and 17 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Case (United States Patent 4,405,317) in view of Takeuchi et al (United States Patent 4,433,107). However, it is the Applicants' position that their claims are not rendered obvious by the collective teachings of Case and Takeuchi and that a prima facie case of obviousness over the cited prior art has not been established.

The Applicants do not believe that any of claims 1, 2, 16, or 17 are obvious over the

collective teachings of Case and Takeuchi. The teachings of Case do disclose a syringe assembly having an actuating plunger. However, the teachings of Case do not disclose or suggest the possibility of manufacturing such actuating plungers with polyisoprene rubber that is synthesized with a neodymium catalyst system. The utilization of such neodymium polyisoprene rubber in manufacturing syringe plunger stoppers is the basis of the invention now being claimed.

The Examiner has combined the teachings of Case with those of Takeuchi. However, the teachings of Takeuchi do not supplement the teachings of Case in a way that renders it obvious to manufacture such syringe plunger stoppers utilizing polyisoprene rubber that is synthesized utilizing a neodymium catalyst system. The teachings of Takeuchi do disclose the synthesis of polyisoprene rubber with a neodymium catalyst system. However, the teachings of Takeuchi do not disclose or suggest that there would be any advantage associated with utilizing polyisoprene rubber that was made with a neodymium catalyst system in making syringe plunger stoppers. In fact, Takeuchi blends such neodymium polyisoprene rubber with another type of rubber and indicates that such blends are useful in industrial goods, such as tires, conveyor belts, hoses, and the like. Takeuchi does not suggest or imply that such compositions would be useful in manufacturing syringe plunger stoppers. In fact, Takeuchi does not indicate that the neodymium polyisoprene rubber would be useful for any purpose without first being blended with a second rubber, such as natural rubber, other commercially available polyisoprene rubber, styrene-butadiene copolymer rubber, polybutadiene rubber, ethylene-propylene copolymer rubber, ethylene-propylene-diene terpolymer rubber, acrylonitrile-butadiene copolymer rubber, butyl rubber, halogenated butyl rubber, and the like. Accordingly, the teachings of Takeuchi do not provide any motivation for a person having ordinary skill in the to utilize neodymium polyisoprene rubber in manufacturing syringe plunger stoppers. Accordingly, the collective teachings of Case and Takeuchi cannot render the utilization of neodymium polyisoprene rubber in manufacturing syringe plunger stoppers obvious.

The advantage of utilizing polyisoprene rubber made with a neodymium catalyst system in manufacturing syringe plunger stoppers is the underlying basis of the invention now being claimed. The teachings of Case and Takeuchi do not suggest or imply that there would be any advantage associated with utilizing neodymium polyisoprene rubber in manufacturing syringe plunger stoppers over natural rubber, other types of synthetic rubber, or synthetic polyisoprene rubber made with alternative catalyst systems. The superiority of neodymium

polyisoprene rubber over other types of polyisoprene rubber for utilization in manufacturing syringe plunger stoppers is not rendered obvious by the teachings of either Case or Takeuchi if viewed either individually or collectively.

The prior art being cited provides no suggestion or motivation to utilize polyisoprene rubber made with a neodymium catalyst system in syringe plunger stoppers. However, the subject patent application shows the unexpected benefits which are realized by utilizing such neodymium polyisoprene rubber in syringe plunger stoppers. Natural rubber contains naturally occurring proteins which can cause an allergic reaction in humans that come in physical contact with the syringe plunger stoppers or even fluids that come in contact with the syringe plunger stoppers. Furthermore, natural rubber is not typically a pure, clean material that can be utilized in manufacturing syringe plunger stoppers that are clear or transparent. Synthetic polyisoprene rubber that is clean and which has low levels of extractable materials can be made with lithium catalyst systems. However, polyisoprene rubber made with lithium catalyst systems is difficult to process and lacks the physical attributes desired for manufacturing syringe plunger stoppers. On the other hand, synthetic polyisoprene rubber having good physical properties can be synthesized utilizing titanium catalyst systems, but contain high levels of foreign substances which is, of course, not desirable in manufacturing products like syringe plunger stoppers where a very clean/clear material is desired. It is the applicants' discovery that polyisoprene rubber made with neodymium catalyst systems offers the best of all worlds in terms of possessing outstanding physical characteristics, being clear, clean, and free of proteins.

These points are made throughout the specification of the subject patent application and are summarized at page 80, lines 13-23 as follows:

As can be seen from the table above, the compounded samples made with the lithium polyisoprene rubber did not exhibit good physical properties. The cured rubber samples made with titanium polyisoprene rubber had had satisfactory physical properties but had high levels of extractable chemical residues. The cured sample made with natural rubber also had satisfactory physical properties but, of course, contained natural rubber protein. Only the cured rubber samples made with neodymium polyisoprene rubber exhibited both good physical properties and low levels of extractable chemical residues.

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None of the cited prior art references disclose, suggest, or otherwise render obvious the unique combination of benefits associated with utilizing neodymium polyisoprene rubber in manufacturing syringe plunger stoppers. Also see benefits described in the specification at page 82, lines 1-11.

**The Rejection under 35 U.S.C. 103(a) over Case in view of Takeuchi and further in view of Throckmorton.**

(1) The Rejection of Claims 3-15, 18 and 19

Claims 3-15, 18 and 19 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Case (United States Patent 4,405,317) in view of Takeuchi et al (United States Patent 4,433,107) and further in view of Throckmorton. The teachings of Throckmorton were combined with those of Case and Takeuchi for the purpose of showing that neodymium catalyst systems that include (1) an organoaluminum compound, (2) an organoneodymium compound, and (3) a labile halide ion are known in the prior art. The Applicants do not dispute this fact that Throckmorton discloses such three component neodymium containing catalyst systems. However, the Applicants do not believe that any person having ordinary skill in the art would turn to the teachings of Throckmorton for the purpose of developing a better stopper for syringe plungers. There is simply no motivation to combine the teachings of Throckmorton with either of the other references. In any case, the Applicants believe that claim 3-15, 18, and 19 allowable over the teachings of the prior art by virtue of the fact that none of the prior art references render obvious the benefits of utilizing neodymium polyisoprene rubber in manufacturing syringe plunger stoppers.

It is believed that the claims of the subject patent application are fully in compliance with the requirements of 35 U.S.C. §103(a) and that the subject patent application is now in a condition for allowance. It is, accordingly, requested that the Examiner's rejections be reversed.

Respectfully submitted,



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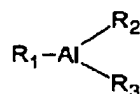
**CLAIMS APPENDIX**

1. A syringe which is comprised of a barrel having a fluid chamber, a proximal end, a distal end and an elongated tip extending from said distal end having a passageway therethrough in fluid communication with said chamber, and an elongated plunger rod including a stopper slidably positioned in fluid-tight engagement with an inside surface of said chamber for drawing fluid into and out of said chamber by movement of said plunger relative to said barrel, wherein the stopper is comprised of neodymium polyisoprene rubber.

2. A syringe as specified in claim 1 wherein the stopper has ribs.

3. A syringe wherein the neodymium polyisoprene rubber is made with a catalyst system that includes (1) an organoaluminum compound, (2) an organoneodymium compound, and (3) at least one compound that contains at least one labile halide ion.

4. A syringe which is comprised of a barrel having a fluid chamber, a proximal end, a distal end and an elongated tip extending from said distal end having a passageway therethrough in fluid communication with said chamber, and an elongated plunger rod including a stopper slidably positioned in fluid-tight engagement with an inside surface of said chamber for drawing fluid into and out of said chamber by movement of said plunger relative to said barrel, wherein the stopper is comprised of neodymium polyisoprene rubber, wherein the stopper has ribs, wherein the neodymium polyisoprene rubber is made with a catalyst system that includes (1) an organoaluminum compound, (2) an organoneodymium compound, and (3) at least one compound that contains at least one labile halide ion, and wherein the organoaluminum compound is of the structural formula:



wherein  $R_1$  is selected from the group consisting of alkyl, alkoxy, aryl, alkaryl, arylalkyl radicals and hydrogen, wherein  $R_2$  is selected from the group consisting of alkyl, aryl, alkaryl, arylalkyl radicals and hydrogen, and wherein  $R_3$  is selected from a group consisting of alkyl, aryl, alkaryl and arylalkyl radicals.



5. A syringe as specified in claim 3 wherein the organoaluminum compound is selected from the group consisting of trimethylaluminum, triethylaluminum, tri-n-propylaluminum, triisopropylaluminum, tri-n-propylaluminum, triisopropylaluminum, tri-n-butylaluminum, triisobutylaluminum, triphenylaluminum, trihexylaluminum, tricyclohexylaluminum, trioctylaluminum, triphenylaluminum, tri-p-tolylaluminum, tribenzylaluminum, ethyldiphenylaluminum, ethyl-di-p-tolylaluminum, ethyldibenzylaluminum, diethylphenylaluminum, diethyl-p-tolylaluminum, and diethylbenzylaluminum.

6. A syringe as specified in claim 3 wherein the organoneodymium compound is of the formula  $NdL_3$  wherein Nd represents neodymium and L is an organic ligand selected from a group consisting of (1) o-hydroxyaldehydes, (2) o-hydroxyphenones, (3) aminophenols, (4) hydroxy esters, (5) hydroxy quinolines, (6) beta-diketones, (7) monocarboxylic acids, (8) ortho dihydric phenols, (9) alkylene glycols, (10) dicarboxylic acids, (11) alkylated derivatives of dicarboxylic acids, and (12) phenolic ethers.

7. A syringe as specified in claim 3 wherein the organoneodymium compound is of the formula  $NdL_3$  wherein L represents an organic ligand containing from 1 to 20 carbon atoms.

8. A syringe as specified in claim 3 wherein the organoneodymium is neodymium naphthenate.

9. A syringe as specified in claim 3 wherein the organoneodymium is neodymium neodecanoate.

10. A syringe as specified in claim 3 wherein the organoneodymium is neodymium octanoate.

11. A syringe as specified in claim 3 wherein the compound that contains at least one labile halide ion is selected from the group consisting of inorganic halide acids, organometallic halides, and inorganic halides.

12. A syringe as specified in claim 11 wherein the compound that contains at least one labile halide ion is an inorganic halide acid selected from the group consisting of hydrogen bromide, hydrogen chloride, and hydrogen iodide.

13. A syringe as specified in claim 11 wherein the compound that contains at least one labile halide ion is an organometallic halide selected from the group consisting of ethylmagnesium bromide, butylmagnesium bromide, phenylmagnesium bromide, methylmagnesium chloride, butylmagnesium chloride, ethylmagnesium iodide, phenylmagnesium iodide, diethylaluminum bromide, diisobutylaluminum bromide, methylaluminum sesquibromide, diethylaluminum chloride, ethylaluminum dichloride, ethylaluminum sesquichloride, diisobutylaluminum chloride, isobutylaluminum dichloride, dihexylaluminum chloride, cyclohexylaluminum dichloride, phenylaluminum dichloride, didodecylaluminum chloride, diethylaluminum fluoride, dibutylaluminum fluoride, diethylaluminum iodide, dibutylaluminum iodide, phenylaluminum diiodide, trimethyltin bromide, triethyltin chloride, dibutyltin dichloride, butyltin trichloride, diphenyltin dichloride, and tributyltin iodide.

14. A syringe as specified in claim 11 wherein the compound that contains at least one labile halide ion is an inorganic halide selected from the group consisting of aluminum bromide, aluminum chloride, aluminum iodide, antimony pentachloride, antimony trichloride, boron tribromide, boron trichloride, ferric chloride, gallium trichloride, molybdenum pentachloride, phosphorus tribromide, phosphorus pentachloride, stannic chloride, titanium tetrachloride, titanium tetraiodide, and tungsten hexachloride.

15. A syringe as specified in claim 3 wherein the atomic ratio of the halide ion to the neodymium is within the range of 0.1:1 to 6:1, and wherein the molar ratio of the organoaluminum compound to the organoneodymium compound is within the range of 4:1 to 200:1.

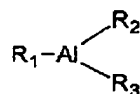
16. A syringe mixing and delivery system comprising a first barrel having an open end and an opposite delivery end defining a delivery passage; a reciprocable stopper sealingly disposed in said first barrel to define a first chamber between said delivery passage and said reciprocable stopper for containing a first constituent in said first chamber; a second barrel

that is sized to be disposed in said first barrel and that has an open end and an opposite discharge end defining a discharge passage; a slidable plunger sealingly disposed within said second barrel to define a second chamber between said discharge passage and said slidable plunger for containing a liquid second constituent in said second chamber; and fluid transfer connector means for operatively connecting said second barrel with said reciprocable stopper to permit flow of said liquid second constituent through said stopper from said second chamber to said first chamber to mix with said first constituent when said second barrel discharge end and plunger are moved closer together whereby subsequent movement of said second barrel and reciprocable stopper together toward said delivery passage of said first barrel expresses the mixed constituents out of said first chamber through said delivery passage, wherein said reciprocable stopper and plunger are comprised of neodymium polyisoprene rubber.

17. A syringe mixing and delivery system as specified in claim 16, wherein said stopper has ribs.

18. A syringe mixing and delivery system as specified in claim 17, wherein the neodymium polyisoprene rubber is made with a catalyst system that includes (1) an organoaluminum compound, (2) an organoneodymium compound, and (3) at least one compound that contains at least one labile halide ion.

19. A syringe as specification in claim 18 wherein the organoaluminum compound is of the structural formula:



wherein R1 is selected from the group consisting of alkyl, alkoxy, aryl, alkaryl, arylalkyl radicals and hydrogen, wherein R2 is selected from the group consisting of alkyl, aryl, alkaryl, arylalkyl radicals and hydrogen, and wherein R3 is selected from a group consisting of alkyl, aryl, alkaryl and arylalkyl radicals.

**EVIDENCE APPENDIX**

**The following documents are attached hereto:**

**NONE**

**RELATED PROCEEDINGS APPENDIX**

**NONE**